

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: State Plan Home Health PDN -New Amendments (#169517)

Rule Number(s): 5160-12-01 (amended); 5160-12-02 (amended); 5160-12-02.3 (amended).

Date: March 20, 2017

Rule Type(s):

New

Amended ☒

5-Year Review

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language. *Please include the key provisions of the regulation as well as any proposed amendments.*

Key Provisions - Home Health (home health) and Private Duty Nursing (PDN) are comprehensive services offered by the Ohio Department of Medicaid (ODM) to eligible individuals, to assist individuals who reside in their home, who without the provision of these services, would otherwise be in a hospital or nursing facility. Home health services are provided on a part-time, intermittent basis and may encompass nursing, aide services, and/or skilled therapies (physical therapy, occupational therapy, and speech-language pathology). PDN services are provided to an individual on a continuous basis and involves skilled nursing services. Both home health and PDN services are Medicaid State Plan benefits available throughout Ohio to individuals of any age.

In this packet, home health and PDN rules 5160-12-01, 5160-12-02, and 5160-12-02.3 of the Administrative Code are being proposed for amendment, primarily to allow home health services

to be provided outside of the place of residence and to allow the Ohio Department of Developmental Disabilities (DODD) the ability to prior authorized private duty nursing services for individuals enrolled on a waiver program administered by DODD. Additional changes were made to clarify roles and responsibilities of entities responsible for authorizing private duty nursing (PDN) services, to correct rule and form citations, and to change terminology used in the rule to ensure consistency with terms used in other Medicaid chapter rules. In addition, typographical errors were corrected, such as reflecting accurate rule citations and removing redundant punctuation.

Proposed Amendments

OAC 5160-12-01, entitled "*Home health services: provision requirements, coverage and service specification*" details the provisions that govern Medicaid home health services as set forth in Chapter 5160-12 of the Administrative Code. This rule is being proposed for amendment to comply with federal regulations that prohibit States from limiting the provision of home health services to services delivered only in the home, or only to services furnished solely to individuals who are homebound. Amendments proposed to this rule include:

- Paragraph (E)(4) is being amended to allow home health services to be provided outside of the individual's place of residence, in any setting in which normal life activities take place, other than a hospital, nursing facility, intermediate care facility for individuals with intellectual disabilities, or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.
- Paragraphs (B), (B)(1), (D)(2)(b), (E)(3)(a)-(b), (G)(2), and (H)(3) are being revised to update references to form, rule and federal citations, and to update terminology used by the ODM (for consistency purposes):
 - In Paragraph (B), a reference to rule 5160-8-21 (recently rescinded) was removed and replaced with 5160-4-04, the current rule pertinent to advanced practice nursing services;
 - In Paragraph (B)(1), the revision date for ODM form 07137 "Certificate of Medical Necessity for Home Health Services and Private Duty Nursing Services" was updated;
 - In Paragraph (D)(2)(b), a rule reference was corrected;
 - In Paragraph (E)(3)(a) – (b), references to the "services plan" are being changed to "person-centered services plan" for consistency purposes to align with similar language used in other ODM rules;
 - The reference to 42 C.F.R. 484.36 in Paragraph (G)(2)(a) is being updated ; and
 - Paragraph (H)(3) is being revised to correct a rule citation.

OAC 5160-12-02, entitled "*Private duty nursing services: provision requirements, coverage and service specification*" specifies the provisions that govern PDN services. Amendments proposed to this rule include:

- Paragraph (A)(4) was deleted, as it was unnecessary;
- In Paragraph (B)(4), language was added to further clarify the residence of the provider is not excluded when the residence of the provider is the same as the individual and all other requirements of Chapter 5160-12 of the Administrative

Code are met;

- Paragraph (G)(5) is being revised to add a possessive apostrophe and the word, "process", for clarity purposes;
- Paragraph (I)(3)(b) is being revised to correct a rule reference (5160-3-09 to 5160-3-08);
- Paragraph (I)(4) is being revised to remove a reference to use of the U5 modifier which is no longer in use;
- Paragraph (I)(5) is being revised to remove unnecessary punctuation, to clarify the role of managed care, and to incorporate provisions that would allow the Ohio Department of Developmental Disabilities (DODD) to prior authorize private duty nursing services;
- Paragraph (J)(4) is being revised to remove references to the U6 modifier which is no longer in use; and
- Paragraph (J)(5) is being amended to clarify the role of managed care, to incorporate provisions to allow DODD to prior authorize private duty nursing services, and to update terminology used by ODM ("all services plan" to "person-centered plan") for consistency purposes.

OAC 5160-12-02.3, entitled "*Private duty nursing: procedures for service authorization*" details how authorization for private duty nursing services is obtained. Amendments proposed to this rule include:

- References to "children and adult" are being changed to "individuals" in Paragraphs (B) and (C) for continuity and to be consistent with other ODM rules;
- Paragraph (C) is being revised to remove references to the Ohio Department of Developmental Disabilities (DODD); and
- Paragraph D is being added to allow DODD to prior authorize private duty nursing services for individuals enrolled on a DODD-administered waiver.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

- RC 5164.02.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

Yes. The proposed amendments will bring Ohio into compliance with 42 C.F.R. 447.70.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

These rules are consistent with, but do not extend beyond, federal requirements.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

OAC rule 5160-12-01 is germane to the statewide administration of Medicaid home health services. The critical objective of this rule is to amplify the provisions for home health services as found in the Code of Federal Regulations, as well as to define the coverage and service specifications explicit to the provision of home health services in Ohio. This rule is necessary as it conveys the critical components of Ohio's Medicaid State Plan as it relates to home health services to individuals, home health providers and their associations.

OAC 5160-12-02 and 5160-12-02.3 are necessary for the statewide administration of Medicaid private duty nursing (PDN) services. The rules enable ODM to comply with federal and/or state requirements that dictate medical necessity be determined in order for PDN services to be covered by ODM, and that the providers of PDN services obtain prior authorization of PDN services before providing such services.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of these regulations will be measured by the safe and effective provision of home health and private duty nursing services furnished by qualified providers who can effectively assess and/or meet the needs of Medicaid recipients.

Development of the Regulations

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation. *If applicable, please include the date and medium by which the stakeholders were initially contacted.*

Academy of Senior Health Sciences	Ohio Department of Mental Health and Addiction Services
Disability Rights Ohio	
Leading Age Ohio	Ohio Department of Aging
Midwest Care Alliance	Ohio Health Care Association
Ohio Association of Area Agencies on Aging	Ohio Department of Medicaid - Managed Care Plans
Ohio Association of Health Plans	Ohio Nurses Association
Ohio Council for Home Care & Hospice	Ohio Olmstead Task Force
Ohio Department of Developmental Disabilities	Ohio Provider Resource Association
Ohio Department of Health	

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The Ohio Department of Medicaid has an existing relationship with stakeholders affiliated with the provision of home health and private duty nursing services in the state, via the Ohio's State Plan Services Workgroup – which includes the organizations listed in response to question 7. The group has been convened on multiple occasions to ensure stakeholder engagement in the rule development process.

The rules in this packet that are being proposed for amendment were presented to the Ohio's State Plan Related Services Workgroup in the summer of 2016 (June and August for OAC 5160-12-01) and in winter of 2017 (March for OAC 5160-12-02 and 5160-12-02.3). The stakeholders recognized the need to bring the state's rules into compliance with the newly imposed federal requirements and were in support of the plans to amend OAC 5160-12-01 to allow home health services to be provided outside of the individual's place of residence and support ODM's plan to allow the Ohio Department of Developmental Disabilities (DODD) to prior authorize PDN services for individuals enrolled on a ODM waiver administered by DODD.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not applicable to the development of these rules.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

None. Alternative regulations were not considered by the Ohio Department of Medicaid as the requirements of these rules are dictated by federal and state laws and regulations. As noted above, the tenets proposed in OAC rule 5160-12-01 are primarily based on requirements prescribed by the Centers for Medicaid and Medicare Services (CMS).

11. Did the Agency specifically consider a performance-based regulation? Please explain.

Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Performance-based regulations are not authorized by statute for home health and private duty nursing services.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The proposed rules were reviewed by policy development staff in consultation with the Ohio Department of Medicaid, Office of Legal Services and the Office of Legislation to ensure there was no duplication.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The final rules will be made available to stakeholders and the general public on the Ohio Department of Medicaid's website.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a) Identify the scope of the impacted business community;

- OAC rule 5160-12-01 impacts approximately 800 Medicare-Certified Home Health Agencies in Ohio. The proposed amendment will allow these providers to furnish home health services in places outside of the individual's place of residence, in any setting in which normal life activities take place, other than a hospital, nursing facility, intermediate care facility for individuals with intellectual disabilities, or any setting in which payment is or could be made under Medicaid for inpatient services that include room and board.
- General changes made to OAC rules 5160-12-02 and 5160-12.02.3 could directly or indirectly impact potentially 3,500 providers of private duty nursing services in Ohio. This includes Medicare certified home health agencies, other accredited agencies, and independent nurse providers, and is broken down as follows:
 - a. 800 certified home health providers
 - b. 100 other accredited agencies
 - c. 2600 independent nurses
- Changes made to OAC rules 5160-12-02 and 5160-12.02.3 will impact the population of individuals enrolled on an ODM Home and Community Based Service waiver administered by the Ohio Department of Developmental Disabilities (DODD), who are in

receipt of private duty nursing (PDN) services. As of February 21, 2017, DODD will be responsible for authorizing PDN services for less than 125 individuals:

Waiver Type	Count
Level One	Less than 50
SELF	Less than 10
IO	Less than 60

b) Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance);

OAC 5160-12-01: This rule requires home health providers to allocate time for the completion of the provider certification process and the allocation of time to report required information to the Ohio Department of Medicaid (i.e., medical necessity of services) using a state specific form. Because of the expansion of the rule (to include additional place settings where home health services may be provided), providers may require more staff in order to cover the provision of services outside of the home.

OAC 5160-12-02: This rule, including proposed revisions, requires private duty nursing providers to allocate time to report required information to the Ohio Department of Medicaid based upon individual plans of care (i.e., certification of medical necessity of services on a state specific form) and to secure authorization prior to the start of services as a condition of compliance.

OAC 5160-12-02.3: This rule, including proposed revision, requires private duty nursing providers to allocate time to secure the authorization as a condition of compliance, prior to the start of private duty nursing services.

c) Quantify the expected adverse impact from the regulation. *The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.*

OAC 5160-12-01 – The amendments being proposed to this rule are primarily the result of an expansion of Medicaid covered services. The revisions will allow services to be provided by Medicare Certified Home Health Agencies (MCHHA) in additional settings, outside of the home, when it is medically necessary to do so. As a result, MCHHA may require automobile and liability insurance for employees who transport individuals, e.g., to and from a doctor’s appointment, or the grocery store. However, costs, such as auto insurance, may currently be the responsibility of the MCHHA’s employee, posing no new costs to the MCHHA, or may be the existing responsibility of the MCHHA, given that the volume of MCHHA in Ohio also

provide other covered services –such as personal aide, private duty nursing, and home care attendant services –outside of the home, and/or at other places in the community under contract with Ohio Medicaid through another programs (e.g., waivers).

Consequently, only the MCHHA not currently authorized to provide services outside of the home (approximately 3.5 to 4 percent) is likely to experience an adverse impact should the need for auto insurance present itself solely due to the proposed changes to this rule.

See table.

Contract Type	Active as of 3/20/2016	Active as of 3/20/2017
ALL Provider Type 60	805	795
Provider Type 60 + (WVNUR and/or WVPCS)	773	768
Percentage of Providers w/o Waivered Svc Contract	4.0%	3.4%

For the MCHHA which solely provides home health services in the home, and is not involved with Medicaid through a waiver program or any other service contract, the cost of liability insurance would vary. Based on factors such as age and marital status, the National Association of Insurance Commissioners, reports the average annual cost for liability coverage in the United States, based on data from the year 2007, was \$475.

OAC 5160-12-02 – The amendment proposed to OAC 5160-12-02 will have no impact on the cost for the provider of obtaining the prior authorization for PDN services. The cost associated with the rule in general remains unchanged: \$175 an hour, per physician, for the time needed to initiate and to secure the required signatures for the medical necessity form (Source: Ohio Council for Home Care and Hospice); as much as \$58 is reported by Midwest Care Alliance to be the cost per plan of care when administrative and skilled nursing staff are considered; and an added \$.25 an hour per patient (a minimum of \$7.25 per visit) can also be attributed to updating the plan of care for skilled care patients as needed.

OAC 5160-12-02.3 - Additional costs attributed to the process of securing signatures and completing the ODM 07137 form, may be incurred at a minimum of 1 hr. of administrative time and .25 hours of nursing time to complete and process the certification of medical necessity once forwarded by the treating physician. As many as 14 staffing hours may be accumulate when intake coordinators, administrator, assistant, clinical managers, billing manager, staffing coordinator, office nurse, and case managers are considered.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Home health and private duty nursing are offered as part of the Ohio’s state plan services and as are subject to certain requirements. Federal and state conditions of participation and compliance with program requirements are required for providers who choose to provide home health and/or private duty nursing services. Providers understand that compliance with

program requirements may include various operating costs including administrative costs (e.g., training, monitoring and oversight, etc.).

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No. The provisions in these rules are mandatory for all home health and private duty nursing service providers.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

ORC section 119.14 is not applicable to these rules.

18. What resources are available to assist small businesses with compliance of the regulation?

Providers in need of assistance may contact the Bureau of Long Term Care Services and Supports, through the Provider Relations Hotline at (800) 686-1516.